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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/815,987

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Yi Yan Yang

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KLARQUIST SPARKMAN, LLP
121 SW SALMON STREET
SUITE 1600
PORTLAND, OR 97204

EXAMINER

AHMED, HASAN SYED

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication..

Office Action Summary	Application No. 10/815,987	Applicant(s) YANG ET AL.	
	Examiner Hasan S. Ahmed	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-34 is/are pending in the application.
- 4a) Of the above claim(s) 20-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicants' amendment and remarks, which were filed on 24 July 2007.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-3, 5, 6, 12, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thombre (US 2003/0175326).

Thombre teaches:

- the sustained-release formulation of instant claim 1 (see paragraph 0026);
- the tablet of instant claim 1 (see paragraph 0017);
- the caffeine of instant claim 1 (see paragraph 0059);
- the poly(ethylene oxide) of instant claim 1 (see paragraph 0093 and Table B);
- the polymer of instant claim 5 (see paragraph 0093 and Table B); and
- the homogenous mixture of instant claim 6 (see paragraph 0068).

Thombre explains that his invention is beneficial because it, "...can be orally administered to a companion animal...without significant loss of the controlled release effect." See paragraph 0011.

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Although Thombe does not provide a specific example using caffeine, working examples in a reference are not required in order to establish a *prima facie* case of obviousness. "A reference can be used for all it realistically teaches and is not limited to the disclosures in its specific examples." See *In re Van Marter et al.* 144 USPQ 421; *In re Wndmer et al.* 147 USPQ 518, 523; and *In re Chapman et al.* 148 USPQ 711. Thombe explicitly discloses caffeine as an active agent in his formulation (see paragraph 0059).

Shaping of the tablet in the form of a donut, as recited in instant claims 12 and 19 is deemed to be a matter of engineering design choice, and thus does not serve to patentably distinguish the claimed subject matter over the prior art. *In re Kuhle*, 526 F. 2d. 553, 188 USPQ 7 (CCPA 1975).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a sustained-release tablet comprising caffeine and a poly(ethylene oxide) polymer, as taught by Thombre. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it can be orally administered to a companion animal without significant loss of the controlled release effect, as explained by Thombre.

*

2. Claims 1 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thombre (US 2003/0175326) in view of Giles, Jr. (US 5,977,120).

Thombre teaches a sustained-release formulation (see above).

The Thombre reference differs from the instant application in that it does not recite kavalactone.

Giles, Jr. teaches a sustained-release composition (see claim 15) comprising:

- the caffeine of instant claim 1 (see col. 2, line 54); and
- the kavalactone of instant claim 11 (see col. 3, line 17).

Giles, Jr. explains that kavalactone is beneficial because of its anti-anxiety effects (see col. 1, lines 44-54).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a sustained-release tablet comprising caffeine, a hydrophilic polymer, and kavalactone, as taught by Thombre in view of Giles, Jr. One of ordinary skill in the art at the time the invention was made would have been motivated to add kavalactone to such a composition because of its anxiolytic effects, as explained by Giles, Jr.

*

3. Claims 1, 4, 7-10, and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thombre (US 2003/0175326).

Thombre teaches a sustained-release formulation (see above)

While Thombre does not explicitly teach percentages of instant claims 4, 7-9, and 13-17, or the release profiles of instant claims 10 and 18, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages and release profiles through routine or manipulative experimentation to

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obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration or release kinetics will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentages or release profiles.

* * * * *

Response to Arguments

Applicant's arguments filed on 24 July 2007 have been fully considered but they are not persuasive.

1. Applicants argue that they, "...can find no example in Thombre where caffeine and poly(ethyl oxide) were combined..." See remarks, page 6.

Examiner respectfully submits that working examples in a reference are not required in order to establish a *prima facie* case of obviousness. "A reference can be used for all it realistically teaches and is not limited to the disclosures in its specific examples." See *In re Van Marter et al.* 144 USPQ 421; *In re Wndmer et al.* 147 USPQ 518, 523; and *In re Chapman et al.* 148 USPQ 711. Thombe explicitly discloses caffeine as an active agent in his formulation (see paragraph 0059). Thombe also

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explicitly discloses poly(ethylene oxide) as an excipient (see paragraph 0093 and Table B).

*

2. Applicants argue that, "...Thombre discloses an enormous genus from which a person might come up with combinations to try." See remarks, page 7.

According to MPEP 2145 (X)(B):

An applicant may argue the examiner is applying an improper "obvious to try" rationale in support of an obviousness rejection. "The admonition that 'obvious to try' is not the standard under § 103 has been directed mainly at two kinds of error. In some cases, what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.... In others, what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (citations omitted) (The court held the claimed method would have been obvious over the prior art relied upon because one reference contained a detailed enabling methodology, a suggestion to modify the prior art to produce the claimed invention, and evidence suggesting the modification would be successful.). See the cases cited in *O'Farrell* for examples of decisions where the court discussed an improper "obvious to try" approach. See also *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) and *In re Ball Corp.*, 925 F.2d 1480, 18 USPQ2d 1491 (Fed. Cir. 1991) (unpublished) for examples of cases where appellants argued that an improper "obvious to try" standard was applied, but the court found that there was proper motivation to modify the references.

Examiner respectfully submits that Thombre has provided a blueprint in his disclosure for the successful use of combination of caffeine and poly(ethylene oxide) in a sustained release formulation (see substantive rejection, above).

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3. Applicants argue that the Giles, Jr. reference does not teach kavalactone and caffeine in a sustained release system. See remarks, page 8.

Examiner respectfully disagrees (see Giles, Jr., claim 15).

* * * * *

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


HUMERA N. SHEIKH
PRIMARY EXAMINER